# MRI Safety Information Resources

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Shellock R & D Services, Inc.

www.MRIsafety.com c

# Websites



## U.S. Food and Drug Administration

Home > Radiation-Emitting Products > Radiation-Emitting Products and Procedures > Medical Imaging

#### Radiation-Emitting Products

#### MRI (Magnetic Resonance Imaging)

- Description
- Uses
- Risks/Benefits
- Information for Patients
- Information for Professionals
- · Laws, Regulations & Performance Standards
- Industry Guidance
- · Other Resources

www.FDA.gov



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ACR Homepage

Joint Commission Issues MRI Sentinel Event Alert

ACR Guidance Document on MR Safe Practices: 2007

Updated ACR Screening Recommendations on Gadolinium-Based MR Contrast Agents, Renal Disease Patients, and Nephrogenic Systemic Fibrosis (NSF)

Institute for Magnetic Resonance Safety, Education, and Research

MRI Safety Web site

Safety Screening Form for MR Procedures (Spanish Version)

Initial FDA Public Health Advisory on Gadolinium-containing Contrast Agents - 6/8/06

Secondary FDA Public Health Advisory on Gadoliniumcontaining Contrast Agents -12/22/06

Latest FDA Public Health Advisory on Gadoliniumcontaining Contrast Agents -5/23/07

The International Center for Nephrogenic Fibrosing Dermopathy Research (ICNFDR)

RadiologyInfo - The radiology information resource for patients - Safety Magnetic Resonance Imaging (MRI)

MRI Quality Control Manual (2004)

#### MR Safety

The ACR created a multidisciplinary blue ribbon panel to address critical issues in MR safety. Initially published in in the American Journal of Roentgenology in June 2002, updated in May 2004, and then markedly expanded and updated in March of 2007 (for June, 2007 publication in the AJR), the ACR Guidance Document for Safe MR Practices: 2007" addresses numerous MR safety related topics, such as:

Static magnetic field-related issues such as translational and rotational forces on ferromagnetic materials

Time-varying magnetic field-related issues such as induced voltage, auditory considerations, and thermal issues

Personnel qualifications and training

Quality & Safety Resources MR Safety

Site access restrictions

Pregnancy-related issues

Guidelines on claustrophobia, anxiety, sedation, analgesia, and anesthesia

Contrast agent safety, including an entire new section and recommendations regarding Nephrogenic Systemic Fibrosis, renal disease patients, and gadolinium administration

An entirely re-written section on the safety of MR scanning of device patients, such as patients with cardiac pacemakers, implanted auto-defibrillators, etc.

MR siting considerations

Emergency preparedness planning

Joint Commission Issues MRI Sentinel Event Alert

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#### Patient Care and Safety

- . Brief overview for the public
- Information for Patients
  - o Patient video from IMRSE
- Safety video for MR workers from IMRSER
- MR contrast agents public comment on NSF
- Safety video for non MR workers from IMRSER
- MR contrast agents
- Regulatory issues for MRI in the UK (and Europe)
- Information for Patients
- Institute for Magnetic Resonance Safety, Education, and Research Frank Shellock
- . International MR Safety Central Web Site Emanuel Kanal
- MRI Safety Frank Shellock
- MR Safety & Patient Comfort GE Medical Systems
- Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD)
- US Food & Drug Administration MRI Safety
- US Food & Drug Administration Guidance for Industry (Issued 14 July 2003)
- <u>US Food & Drug Administration</u> Public Health Notification (Issued 10 May 2005)

www.ISMRM.org



#### Institute for Magnetic Resonance Safety, Education, and Research

Home

#### List of Videos Available on IMRSER

MRI Related Videos

Ordering Information for FREE MRI VIDEOS can be found by scrolling to the bottom of this page...

Functions a	bne
Activities	

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MRI Personnel

Video Title	Video Description	
(dick title below to view video now)	250	
MRI Safety for MRI Professionals	In consideration of the critical components of a comprehensive MRI safety program, this lecture provides an overview of MRI bioeffects related to static, gradient (time-varying), and radiofrequency electromagnetic fields. Dr. Frank G. Shellock will discuss safety guidelines and recommendations developed for MRI facilities, terminology changes for implants and devices, and provide up-to-date information pertaining to implants that have undergone evaluation in the MRI environment. Information specific to scanners operating at 3-Tesla is included (one hour video).	
	This 20 minute video is intended for patients and explains basic aspects of the MRI examination.	
	An MRI system uses a nowerful magnetic field that is always on	

MRI Safety for Non-MRI environment in the event of an emergency, can prevent

and injuries in the MRI environment.

even when the scanner is not in use. The magnetic field is invisible and can cause accidents, injuries, and damage to equipment if special precautions are not taken. Anyone who

works in or around an MRI facility, or who may encounter the

This 15-minute presentation is intended for individuals who may encounter the MRI environment. This video will provide you with the basic safety information you need to know to avoid accidents

accidents and injuries by knowing basic information.

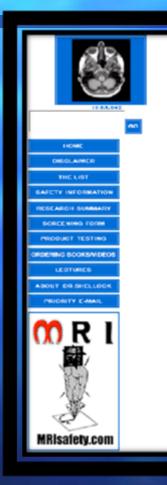
www.IMRSER.org

# FREE! MRI Safety Training Videos



- ✓NO need to register, FREE to all site visitors
- ✓Information for all aspects of MRI safety
- √Thousands of implants/devices tested, including 3-Tesla
- ✓Many "electronically-activated" implants have MR labeling approved by the FDA
- ✓Email questions, as needed

## 150+ Topics for MRI Safety



#### Safety Information

- 3.0-Tesia MR Safety Information for Miscellaneous Implants and Implants and Devices
- AccuRx Constant Flow Implantable Pump and Duracath Intraspinal Catheter
- Acoustic Noise and MRI Procedures Environment
- Actipatch
- Activa (Neurostimulation) System (Medtronic, Inc., Minneapolis, MN)
- Alsius Intravascular Temperature Management
- Aneurysm Clips
- Baha, Bone Conduction Implant
- Bloeffects of Gradient Magnetic
- Bioeffects of Radiofrequency Fields
- Bioeffects of Static Magnetic Fields
- Biopsy Needles, Markers and Devices
- Body Piercing Jewelry and MRI
- Bone Fusion (Spinal) Stimulator
- BRAVO pH Monitoring System
- Breast Tissue Expanders and Implants
- Cardiac Pacemakers and Implantable Cardioverter Defibrillators (ICDs)
- Cardiovascular Catheters, Other Catheters, and Accessories
- Carotid Artery Vascular Clamps

- Devices
- "Missile Effect" Accidents and Prevention
- Monitoring Patients in the MR
- MRI Contrast Agent Safety
- MRI Contrast Agent: Magnevist -Product Insert Information
- MRI Contrast Agent: MultiHance -Product Insert Information
- MRI Contrast Agent: Omniscan -Product Insert Information
- MRI Contrast Agent: ProHance -Product Insert Information
- MRI Contrast Agents and Adverse Reactions
- MRI Contrast Agents and Breast Feeding Mothers
- MRI Contrast Agents and Nephrogenic Systemic Fibrosis
- MRI Contrast Agents and Nephrogenic Systemic Fibrosis (NSF): Review Article
- MRI Contrast Agents and NSF: Websites and Links to Obtain Current Information
- MRI Contrast Agents and Pregnant **Patients**
- MRI Information for Patients
- MRI Issues for Hemodynamic

## The Role of the FDA

- Help increase awareness of MRI safety issues
- Update and add information including links to FDA website

## Textbooks

Shellock FG, Kanal E. MAGNETIC RESONANCE: BIOEFFECTS, SAFETY AND PATIENT MANAGEMENT. Raven Press, New York, 1994 and 1996; *Two editions* 

Shellock FG. GUIDE TO MRI PROCEDURES AND METALLIC OBJECTS: UPDATE 1994. Raven Press, New York, 1994 - 2001; Seven editions

Shellock FG. MAGNETIC RESONANCE PROCEDURES: HEALTH EFFECTS AND SAFETY. CRC Press, Boca Raton, FL, 2001.

Shellock FG. REFERENCE MANUAL FOR MAGNETIC RESONANCE SAFETY, IMPLANTS, AND DEVICES: 2004 EDITION. Biomedical Research Publishing Group, Los Angeles, CA, 2002 to 2011; *Ten editions, new edition each year* 

### Summary - Role of the FDA

- Sponsor MRI safety workshop or other meeting
- Conduct research to identify areas that are problematic or that need improvement
- Advise and educate the MRI community (i.e., like paper from Hardy and Weils)
- Develop in-house standards for MRI labeling and disseminate to all FDA reviewers

- Help to increase awareness of MRI safety issues
- Update and add information and links to FDA website

## Thank you!